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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,368	09/28/2004	Joachim Bunger	MERCK-2926	3834
23599 7590 03/18/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER HUGHES, ALICIA R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
03/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,368

Applicant(s)

BUNGER ET AL.

Examiner

ALICIA R. HUGHES

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 4-15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 3 sheets.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-20 are pending. However, only claims 3 and 16 are the subject of this Office Action.

Applicants' arguments, filed on 08 December 2008, have been fully considered and are deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is enabled for the protection of human skin against premature aging. However, the claimed prophylaxis the same is not supported by the specification. As a result, the effect of performing the invention by one skilled in the art would be that of undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in organic chemistry is high, the results of experiments to discover treatments for the illnesses and conditions recited in claim 17, is unpredictable. While all of the Wands factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The applicant has provided a number of working examples for producing chemical compositions that treat wrinkling. However, the applicant has failed to enable the prophylaxis, or prevention, of any of the above conditions noted in the claimed invention through the examples provided. Prophylaxis is generally regarded as the preventing of disease.

As such, the art of the claimed invention lacks predictability because the claim as written to include prophylaxis of edema, cardiac enlargement, body fluid retention, and hydrothorax is drawn too broadly.

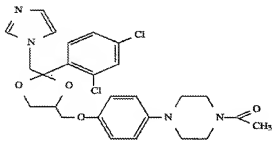
Claim Rejection – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,476,852 [hereinafter referred to as "Cauwenberg"] in view of Mohammad, Taj, "Laser-induced In Vitro Isomerization of Urocanic Acid in UVA Region and the Origin of Excited Triplet State," *Tetrahedron Letters*, Vol. 43, pages 8897-8900 (2002)[hereinafter referred to as "Mohammad"].

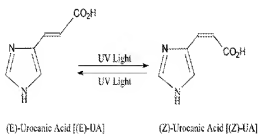
Cauwenberg et al disclose ketoconazole, (+)-cis-1-acetyl-4-[4[[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine, as reflected below



as effective in treating subjects affected by the photoaging of the skin (Col 1, lines 45-63 and Col. 2, lines 50-55). The same is usable in a pharmaceutically acceptable acid addition salt form as well as solvates (Col. 2, lines 1-20) and can be used alone (Col. 4, lines 16-23).

Mohammad discloses urocanic acid, 2-propenoic acid, 3-[1H-imidazol-4(5)-yl][hereinafter referred to as "Urocanic acid"], as reflected below, as a chemical of interest to

photochemists, medicinal chemists, and immunologists, etc due to its light absorbing properties and presence in the upper layer of mammalian skin (Page 8897, Col. 1, Para. 1) and that the same and its chemical reactivity with biological molecules in excited states have consequences in the photoaging of the skin (Page 8900, Col. 1, Para. 2).



The teachings of Mohammad would motivate one of ordinary skill in the art to modify the teachings of Cawenberg to reach the instant invention given the overlapping subject matter, most notable the administration of imidazol compounds to treat photoaging in skin.

In view of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was claimed to use the compounds of formula 1a and 1b to treat protect the human skin against aging.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614